

Attorney Docket No.: DEX-0117  
Inventors: Salceda et al.  
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a<sup>1</sup> (c) a polynucleotide which is capable of hybridizing under stringent conditions to the antisense sequence of SEQ ID NO: 1, 2, 3, 4, 5, 18 or 20.

3. A method for diagnosing the presence of breast cancer in a patient comprising:

a<sub>2</sub> (a) determining levels of Breast Cancer Specific Gene (BCSG) in cells, tissues or bodily fluids in a patient; and

(b) comparing the determined levels of BCSG with levels of BCSG in cells, tissues or bodily fluids from a normal human control, wherein an increase in determined levels of BCSG in said patient versus normal human control is associated with the presence of breast cancer.

Amended 4. (amended) A method of diagnosing metastases of breast cancer in a patient comprising:

(a) identifying a patient having breast cancer that is not known to have metastasized;

(b) determining Breast Cancer Specific Gene (BCSG) levels in cells, tissues, or bodily fluid from said patient; and

(c) comparing the determined BCSG levels with levels of BCSG in cells, tissue, or bodily fluid of a normal human control, wherein an increase in determined BCSG levels in the patient versus

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the normal human control is associated with breast cancer which has metastasized.

5. (amended) A method of staging breast cancer in a patient having breast cancer comprising:

- Q2
- (a) identifying a patient having breast cancer;
  - (b) determining Breast Cancer Specific Gene (BCSG) levels in a sample of cells, tissue, or bodily fluid from said patient; and
  - (c) comparing determined BCSG levels with levels of BCSG in cells, tissues, or bodily fluid of a normal human control, wherein an increase in determined BCSG levels in said patient versus the normal human control is associated with breast cancer which is progressing and a decrease in the determined BCSG levels is associated with breast cancer which is regressing or in remission.
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6. (amended) A method of monitoring breast cancer in a patient for the onset of metastasis comprising:

- (a) identifying a patient having breast cancer that is not known to have metastasized;
- (b) periodically determining levels of Breast Cancer Specific Gene (BCSG) in samples of cells, tissues, or bodily fluid from said patient; and

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(c) comparing the periodically determined BCSG levels with levels of BCSG in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG levels in the patient versus the normal human control is associated with breast cancer which has metastasized.

7. (amended) A method of monitoring a change in stage of breast cancer in a patient comprising:

Q2 (a) identifying a patient having breast cancer;

(b) periodically determining levels of Breast Cancer Specific Genes (BCSG) in cells, tissues, or bodily fluid from said patient; and

(c) comparing the periodically determined BCSG levels with levels of BCSG in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined BCSG levels in the patient versus the normal human control is associated with breast cancer which is progressing in stage and a decrease is associated with breast cancer which is regressing in stage or in remission.

8. A method of identifying potential therapeutic agents for use in imaging and treating breast cancer comprising screening molecules for an ability to bind to Breast Cancer Specific Gene (BCSG) wherein the ability of a molecule to bind to BCSG is